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**STATE OF DELAWARE
BOARD OF PHARMACY**

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, April 19, 2017 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	May 17, 2017

MEMBERS PRESENT

Susan Esposito, R.Ph., Professional Member, President
Hooshang Shanehsaz, R.Ph., Professional Member, Vice President
Bonnie Wallner, R.Ph., Professional Member
Tejal Patel, PharmD, Professional Member
Jay Galloway, Public Member
Gayle MacAfee, Public Member

MEMBERS ABSENT

Kimberly Robbins, R.Ph., Professional Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

David Dryden
Lindsay Orr
Jeenu Philip
Miriam Mobley-Smith
Rick Hillbom
Amy Boyett
Tim DeRose

CALL TO ORDER

Ms. Esposito called the meeting to order at 9:35 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Shanehsaz and seconded by Ms. MacAfee to approve the meeting minutes for March 15, 2017 with corrections. The motion carried.

UNFINISHED BUSINESS

Public Hearing – Proposed Regulation Changes Sections 1.4.1, 1.2.4, 17.0, 5.1.7 – Ms. Kelly opened the hearing with an explanation of the proposed changes. There being no written or public comment received Ms. Kelly requested that “Deliberations” be added to the May agenda. The hearing concluded.

Statutory and Regulatory Discussion

Senate Bill 44 – PMP Registration – Ms. Kelly read the bill and provided explanation.

Senate Bill 45 – U47700 “Pinky” – Ms. Kelly read the bill and provided explanation.

A motion to move to agenda item IV.1.2 Dispensing of Naloxone – Jamie Mack, Div. of Public Health was made by Mr. Shanehsaz and seconded by Ms. Patel. The motion carried. Mr. Mack provided information on standing orders regulations updates that would allow for all FDA approved formulations of Naloxone to be dispensed and administered. He also explained that a training certificate would be provided at the completion of the required training. This certificate could then be provided to the pharmacy to substantiate that the required training had been received. Pharmacists are required to provide counseling and training. Record keeping requirements continue to be formulated. Currently a prescription is required for everyone with the exception of first responders. First responders receive their supply of naloxone under the Division of Public Health’s standing order. Division of Public Health and Emergency Medical Services are responsible to ensure that all expiration requirements are adhered to. They are hopeful that the effective timeline for these changes are May 2017.

Senate Bill 48 Naloxone Ms. Kelly read the bill and provided explanation.

Prescriptive Prescriber Contact Information – this is a statutory change that will require further review. This item will be moved back to the legislative committee in May. Ms. Kelly will provide the committee with additional information for review.

Review of Regulation 5.2.4 Patient Counseling - Ms. Kelly provided draft regulation changes for the Board to review. Ms. Kelly reviewed the current language vs proposed changes. A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to move this item back to the legislative committee for further discussion and review in May. The motion carried.

Telemedicine Pharmacy Regulations Change – Mr. Shanehsaz spoke regarding disclosure that he is employed by Cardinal Health and disclosure of this should have occurred prior to Cardinal Health’s presentation to the Board during April’s meeting. This was an oversight on his part; he apologized for any confusion this may have caused. Ms. Kelly stated that the Division of Professional Regulation is not in support of either the registration or the licensure of pharmacy technicians. A motion was made by Ms. Patel seconded by Ms. MacAfee to move this item back to the legislative committee for further discussion and review in May. The motion carried.

3PL Licensure – A motion was made by Mr. Shanehsaz and seconded by Ms. MacAfee to move this item back to the legislative committee for further discussion and review in May. The motion carried.

PRESIDENT’S REPORT

Ms. Esposito provided the following report:

CE Audits: On March 20th, I completed the CE audits that were compiled by our team. Letters of follow up were sent to those who have not complied with the audit or need to send additional documentation.

Health Presentation DPS: I presented a session on Diabetes on Friday March 24th in Greenwood, with assistance from Beebe’s Health Population Division. Additional programs are being offered around the state and pharmacist Jessica Spence presents at the Greenwood Cheers center monthly on health topics.

DPS: A question has been forwarded to the Board from a recent MTM Session which I will ask to be added to new business for us to discuss. The question was whether HIPAA requirements apply to non-pharmacy employees who are used to translate prescription related information to a patient.

Investigative Case: I was approached as the contact for a current case against a healthcare provider in Sussex County. The case is being sent to the Attorney General's Office for processing and further action. The case may come before you at a future Board Meeting.

NEW BUSINESS

Ms. Esposito read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

Gunjan	H	Kamdar	A1-0005051
Anh	H	Vu	A1-0005052
Sarah	J.	Lim	A1-0005053
Levette	A	Owusu-Ansah	A1-0005054
Scott	Andrew	Hoffman	A1-0005055
Krupa	K.	Patel	A1-0005056
Donna	M.	Kemp	A1-0005057
Joseph	S.	Crisafulli	A1-0005058
Zachary	M.	Rodgers	A1-0005059
Veronica	A.	Crowder	A1-0005060

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

Boniface	S.	Fogwe	A7-0002449
Joan	N.	Witte	A7-0002450
Jessica	Paulistin	Marcelin	A7-0002451

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

NYC Wholesale Inc., d/b/a Moon Pharmacy	A9-0001977
MN Pharmacy dba PillPack Miami	A9-0001978
Walgreens #02445	A9-0001979
Novixus Pharmacy Services	A9-0001980
Pharmacena Labs LLC	A9-0001981
Carepoint Rx	A9-0001982
Prime Therapeutics Specialty Pharmacy LLC dba Prime Therapeutics	A9-0001983

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Non Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

Sourceone Healthcare Technology Inc	A4-0001171
PharmaLink, Inc.	A4-0002026
UPS Supply Chain Solutions, Inc.	A4-0002390
Westminster Pharmaceuticals, LLC	A4-0002393
Nitrous Oxide Corp	A4-0002394
Nephron SC, Inc.	A4-0002395
Kuehne + Nagel Inc	A4-0002396
Medinatura, Inc.	A4-0002397
Pharmaceutical Trade Services, Inc. dba Durbin USA	A4-0002398

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

The PromptCare Companies, Inc.	A2-0000146
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A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Medical Gas Distributor applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

None

Non-Retail Pharmacy Licensure Approval Ratification

None

Outsourcing Facility

Nephron SC, Inc. AD-0000038

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Outsourcing Facility application. The motion unanimously carried.

Pharmacist-In-Charge Interviews

None

Review of Consent Agreement

Valerie Denise Barnes - A motion was made by Ms. Patel and Ms. Wallner to reject the consent agreement as written. The following disciplinary recommendations were made: a letter of reprimand, fine, and 15 additional continuing education credits to include infection control, hazardous waste and patient safety and ethics, which must be completed within 90 days of the date of the final order. The motion unanimously carried. Ms. Kelly will respond to the Attorney General's office with this outcome and recommendation.

Jaime L McGee - A motion was made by Ms. Patel and Ms. Wallner to reject the consent agreement as written. The following disciplinary recommendations were made: a letter of reprimand, fine, and 15 additional continuing education credits to include infection control, hazardous waste and patient safety and ethics, which must be completed within 90 days of the date of the final order. The motion unanimously carried. Ms. Kelly will respond to the Attorney General's office with this outcome and recommendation.

Board Review of Facility Applications

Owens and Minor Distribution, Inc. (IL) - A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to table the application for more information. The motion unanimously carried.

Sorkins Rx LTD (NY) - A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to approve the application. The motion unanimously carried.

Mallinckrodt Nuclear Medicine, LLC. (MO) - A motion was made by Mr. Galloway and seconded by Mr. Shanehsaz to approve the application. The motion unanimously carried.

Continuing Education Review

None

Pharmacist and Pharmacy - Discussion/Action Items

Delaware Hospice Pyxis – Upgrade Review – the Board requested Michelle McCreary, Pharmacist Compliance Officer to contact Delaware Hospice for clarification and inspection if required.

Dispensing of Naloxone – Jamie Mack, Division of Public Health – this agenda item was heard and discussed earlier in the agenda.

COMMITTEE REPORTS

Legislative – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz, Bonnie Wallner and Gayle MacAfee

Mr. Shanehsaz stated that the committee discussed tele-pharmacy and the committee will need to review the definition of a pharmacy technician and the qualifications of a pharmacy technician. No further information has been received from Delaware Health Information Network (DHIN).

Continuing Education – Bonnie Wallner, Tejal Patel:

No Report

Consumer Affairs – Jay Galloway, Gayle MacAfee

No Report

Professional Liaisons – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

Controlled Substance Liaisons –Tejal Patel, Hooshang Shanehsaz:

None

INSPECTION and PMP REPORT - Michelle McCreary, Samantha Nettesheim

Ms. McCreary stated she has completed the following inspections:

- 1 – Change of Ownership Inspection
- 1 – Beebe Hospital CMS Validation Service Inspection (4 days)

NEWSLETTER UPDATES

Copy was submitted to National Board of Pharmacy (NABP) to be published on the 15th of April.

BOARD CORRESPONDENCE

Ms. Esposito read the following correspondence received:

Christiana Care - J. McPoland - National Take Back

NABP - Press Release - Statewide Protocol

Ryan Greenly Letter – the Board requested that a letter of response be completed and sent notifying Mr. Greenly that Delaware currently has no schools of pharmacy, there is no collaborative care statute or regulation that allows this practice. He should contact professional organizations and get involved. Ms. Esposito will draft a letter to be sent.

Elsevier Inc. - Clinical Pharmacology Letter – the Board requested a letter be sent to notify Elsevier that no approval is needed as regulation 3.3.2 covers this. The Board does not maintain a listing of these resources.

Lisa A Lusk - e-supplement US Gov Accountability Office

NABP - Rogue Internet Drug Outlets Contribute to Antibiotic-Resistant Infections

OTHER BUSINESS BEFORE THE BOARD

Ms. Esposito asked what the HIPAA requirements are related to providing translation to a patient by non-pharmacy personnel who have not had the required HIPAA compliance training. The Board has no opinion; the use of certified interpreters should be used in non-emergent situations.

PUBLIC COMMENT

None

NEXT SCHEDULED MEETING

The next meeting is scheduled for May 17, 2017 at 9:30 Am., 2nd Floor Conference Room.

ADJOURNMENT

There being no other business before the Board a motion to adjourn the meeting was made by Mr. Shanehsaz and seconded by Ms. Patel at 11:57 am. The motion unanimously carried.

Respectfully submitted,



Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy